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## Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Application No. Applicant(s) 09/832 770 DE LA HUERGA, CARLOS Office Action Summary Examiner Art Unit Vit W. Miska 2833 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 29 October 2009. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1.4.5.7-10.12-40 and 154-158 is/are pending in the application. 4a) Of the above claim(s) 12-14, 16, 18-21, 30-32, 34, 35, 37-40 and 156-158 is/are withdrawn from consideration. Claim(s) is/are allowed. 6) Claim(s) 1.4.5 and 7-10.15.17.22-29.33.36.154.155 is/are rejected. 7) Claim(s) \_\_\_\_\_ is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner, Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) ☐ All b) ☐ Some \* c) ☐ None of: Certified copies of the priority documents have been received. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s)/Mail Date. \_\_\_ Notice of Draftsperson's Patent Drawing Review (PTO-948)

Paper No(s)/Mail Date

3) Information Disclosure Statement(s) (PTO/SB/08)

5) Notice of Informal Patent Application

6) Other:

Art Unit: 2833

#### DETAILED ACTION

 Upon further review, the allowance of all claims previously allowed is withdrawn for the reasons set forth below.

### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- Claims 1,7,8,4,5,17,154 and 155 rejected under 35 U.S.C. 103(a) as being unpatentable over McIntosh et al (5088056) in view of O'Brien (6150942).
- 3. With respect to claims 1, 17, 154 and 155, McIntosh et al disclose a medication system for performing at least one health safety function (alerting user to take medication), the system comprising:

at least one container 15 (vial) for holding doses of medication, the container having a memory device (bar code in Fig. 3 and col. 9, line 13-19) containing specifying information useable to determine a prescribed dosing regimen for the medication (col. 10. lines 50-58):

Application/Control Number: 09/832,770

Art Unit: 2833

a communication device 32, 60, 64;

a timing device 54 (col. 10, line 32);

display 18; and

a processor 54 and an associated surface 14, the processor for receiving the specifying information when the memory device is proximate the surface, the processor linked to the timing device and linkable to the communication device (see Fig. 4);

wherein, prior to an initial time the specifying information has not been received by the processor and, at the initial time the memory device is disposed proximate the surface and the processor receives the specifying information for the first time, the first time the processor receives the specifying information, the processor using the specifying information to identify prescribed dosing regimen information and performing at least one health safety function as a function of the prescribed dosing regimen information; and

wherein, the processor further uses the prescribed dosing regimen information to determine a predetermined time to take the medication (col. 10, lines 50ff), uses the timing device to identify the predetermined time and causes the communication device to indicate when the predetermined time occurs (col. 10, line 66).

4. With respect to the language of the next to the last paragraph of claim 1, the functional language is met in McIntosh et al with the description at col. 10, lines 50ff of ROM 56 containing preprogrammed information regarding the prescribed dosing regimen of commonly prescribed medications, such that when medication container 15

Art Unit: 2833

is placed adjacent surface 14 of the apparatus for the first time, the specifying information obtained by the code reader is input to processor 54 for retrieving the prescribed dosing regimen corresponding to the specified medication.

5. McIntosh does not suggest the processor for receiving the specifying information using radio frequency. However, the memory device and associated bar coder reader (optical reader) disclosed in McIntosh et al is one of several possible identification devices available at the time the invention was made. O'Brien discloses a medication system with container 9 or vial of Fig. 7 having a memory device 1.11 (RFID or bar code) and processor 8, 7 for receiving the specifying information for identifying a dosing regimen. The memory device may be either a bar code or an RFID tag (col. 4, line 29) and the processor may contain corresponding receiving means. Thus, one of ordinary skill in the art, having both references, would be have a suggestion of using radio frequency technology for retrieving information from a medication container in the McIntosh et al apparatus, in place of the disclosed optical memory and reader, as taught by O'Brien. Such modification would constitute obvious substitution of identification devices with well known devices for performing similar functions. The fields of endeavor being related, the advantages of radio frequency type tags over optical types, specifically of the capability to detect without orientation limitations, would be evident to one of ordinary skill in the art in the device of McIntosh et al in view of the disclosure of O'Brien.

Application/Control Number: 09/832,770

Art Unit: 2833

6. Regarding the claims 7,8,4 and 5, an aligner corresponds to the portions or walls of compartments 14 adjacent the medication containers when the latter are placed therein. Such aligners correspond to "indicia" (in the same manner as applicant's claimed indicia).

Page 5

- Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over McIntosh et al (5088056) and O'Brien (6150942), as applied to claim 1, above, in further view of Mucciacciaro (5239491).
- 8. McIntosh et al. do not suggest aligners wherein the facing surfaces of the containers and the aligners have the same shape. Such modification, however, would be an obvious means for facilitating placement of containers 15 in surfaces 15.

  Mucciacciaro teaches placement of medication containers 4 on surface 2 of holder 1, the latter having aligners 3 for supporting associated container facing surfaces 5. It would be obvious for one of ordinary skill in the art to provide such aligners in McIntosh et al. by making bottom surfaces of containers 15 of shape to correspond to shapes of aligners in bottom of compartments 14 in order to assist the user with placement of the containers on proper sensing areas of the compartments.

Art Unit: 2833

9. Claims 15, 22-28, 33 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glynn (5,774,865) in view of O'Brien (6150942) and McIntosh et al (5088056). Glynn discloses an apparatus and method for performing health safety functions including containers 1,2,4 for holding doses of medication, machine readable and writable memory strips 3,5,7, respectively, containing specifying information (medicine identity, col. 4, line 38) usable to determine a prescribed dosing regimen (col.4, line 57-58), sensor 13 with sensor area 9 for receiving several specifying devices 3,5,7 receiving the specifying information, sensor 13 linked to, processor 21 (Fig. 4B), using the information to identify a prescribed dosing regimen (col. 5, line 18), and performing a health safety function (alarm reminders, col. 5, line 29), processor 21 retrieves specifying information from each of the memory devices (col. 5, lines 67), display 33.

10. Glynn does not suggest using RF communication for receiving information from the memory devices by the sensor or processor. The preferred embodiment employs bar code labels 3,5,7, and a bar coder reader a sensor 13 for reading labels 3,5,7. However, other alternatives for the bar code type system are suggested at col. 6, lines 21 and 33, including laser transceivers and magnetic media. Thus, one of ordinary skill in the art would be taught to employ suitable available technology for storing medication data in containers 1,2,4 and corresponding retrieving means 9,13. O'Brien has been identified above and teaches use of radio frequency labels RFID on the bottom surface of medication containers (Fig. 7) and corresponding RFID reader 8 for

Application/Control Number: 09/832,770

Art Unit: 2833

identifying medication therein. One of ordinary skill in the art having both references would therefore have a suggestion of using this type of radio frequency device for storing and retrieving information from the memory device in place of the bar code reader suggested by Glynn, as an obvious alternative for achieving the benefits of radio communication such as greater reception area and distance, less sensitivity, etc. not associated with optical bar coder readers.

Page 7

- 11. With respect to last paragraph of claim 22, Glynn apparently inputs the medication and dosage information manually with the aid of the bar code reader (col. 4, lines 32-56), and does not appear to suggest that when the specifying device is received for the first time proximate the sensor, the specifying information is used to identify a dosing regimen. However, whether the specifying information in Glynn is stored in the RAM by the user scanning the containers or is programmed in the ROM 49 prior to use of the device would be a matter of obvious choice to the designer. If sufficient memory space were available in the ROM, then one of ordinary skill in the art would recognize that all medication and dosage information could be previously stored therein and without the need of the user inputting such data.
- 12. Further, McIntosh et al disclose the medication system identified above and suggest at col. 10, lines 50ff a ROM 56 containing preprogrammed information regarding the prescribed dosing regimen of commonly prescribed medications, such that when medication container 15 is placed adjacent surface 14 of the apparatus for

Art Unit: 2833

the first time, the specifying information obtained by the code reader is input to processor 54 for retrieving the prescribed dosing regimen corresponding to the specified medication. In view of the similar fields of endeavor of Glynn and McIntosh et al, the advantages of storing in a memory identity medication and dosage information prior to use of the medication apparatus as suggested by McIntosh et al, would be recognized by one of ordinary skill in the art in the apparatus of Glynn. Clearly, the size and cost considerations of the device of Glynn will dictate to one skilled in the art how much data may be stored in ROM 49.

- 13. Regarding claim 23, Glynn further does not disclose a communication device for indicating which medication to consume by indicating the containers. McIntosh et al disclose a medication device with communication devices including separate visual indicators 32 adjacent medication containers indicating the medication to be consumed. It would be obvious for one of ordinary skill in the art having both references to provide a visual warning indicator in the Glynn system for identifying each container, as done in McIntosh et al, as an obvious means for prompting the user to take the medication from the correct container.
- 14. With respect to claims 24-28, Glynn further includes timing means inherently associated with processor 21 for providing the predetermined times for taking medication (col. 5, lines 18, 29), and the processor using the specifying information (medicine identity) to identify a dosing regime, as noted above. Separate sensing areas

Art Unit: 2833

for each container are suggested in the embodiment describe at col. 6, lines 45-47, wherein the partitions comprise the claimed aligners. Facing surfaces 3,5,7 of the containers are disclosed facing sensing areas (scanners) at col. 6, lines 46-47.

- 15. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Glynn (5,774,865), O'Brien (6150942) and McIntosh et al (5088056), as applied to claim 28, above, in further view of Mucciacciaro (5239491).
- 16. Glynn does not suggest aligners wherein the facing surfaces of the containers and the aligners have the same shape. Such modification, however, would be an obvious means for facilitating placement of containers 1,2,4 onto tray 9. Mucciacciaro teaches placement of medication containers 4 on surface 2 of holder 1, the latter having aligners 3 for supporting associated container facing surfaces 5. It would be obvious for one of ordinary skill in the art to provide such aligners in Glynn by making bottom surfaces of containers 1,2,4 of shape to correspond to shapes of aligners in bottom of tray 9 in order to assist the user with placement of the containers on proper sensing areas of the tray.
- 17. In view of the rejection of previously allowed claims, the withdrawal of the restriction requirement of 2/26/2004 in the Office action of 1/22/2009 as to any claim that requires all limitations of an allowable claims is vacated. The original restriction

Art Unit: 2833

requirement is reinstated for all claims previously indicated as being withdrawn and subsequently allowed in view of dependence on allowed claims.

 Claims 12-14, 16, 18-21, 30-32, 34, 35, 37-40 and 156-158 are withdrawn from consideration as being directed to non elected species.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vit W. Miska whose telephone number is 571-272-2108. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Renee Luebke can be reached on 571-272-2009. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 2833

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Vit W. Miska/ Primary Examiner, Art Unit 2833

Art Unit: 2833